Q3/FY2020 FINANCIAL RESULTS
ENDED DECEMBER 31, 2020

Naoki Okamura
Executive Vice President,
Chief Strategy Officer and Chief Financial Officer
Astellas Pharma Inc.
January 29, 2021
CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management’s current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas’ intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.
AGENDA

I  Q3/FY2020 Consolidated Financial Results

II  Initiatives for Sustainable Growth
Revenue and profit are in line with assumptions of full-year forecast

- Revenue and Core operating profit decreased, YoY
- Sales of growth drivers steadily increased
- Spending of SG&A and R&D expenses is on track
- No changes have been made to FY2020 forecast
## Q3/FY2020 FINANCIAL RESULTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q3/FY19</th>
<th>Q3/FY20</th>
<th>Change</th>
<th>Change (%)</th>
<th>FY20 FCST</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td>988.5</td>
<td>940.9</td>
<td>-47.6</td>
<td>-4.8%</td>
<td>1,256.5</td>
<td>74.9%</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>221.6</td>
<td>187.7</td>
<td>-33.9</td>
<td>-15.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of revenue</td>
<td>22.4%</td>
<td>20.0%</td>
<td>-2.5 ppt</td>
<td>-15.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SG&amp;A expenses</strong></td>
<td>353.6</td>
<td>363.0</td>
<td>+9.5</td>
<td>+2.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>159.8</td>
<td>168.8</td>
<td>+9.1</td>
<td>+5.7%</td>
<td>233.5</td>
<td>72.3%</td>
</tr>
<tr>
<td>Amortisation of intangible assets</td>
<td>15.4</td>
<td>17.3</td>
<td>+1.9</td>
<td>+12.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Core operating profit</strong></td>
<td>235.9</td>
<td>203.7</td>
<td>-32.2</td>
<td>-13.6%</td>
<td>251.0</td>
<td>81.2%</td>
</tr>
</tbody>
</table>

*<Full basis>*

<p>| | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Other income</td>
<td>15.1</td>
<td>7.0</td>
<td>-8.0</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other expense</td>
<td>13.4</td>
<td>51.3</td>
<td>+38.0</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Operating profit</strong></td>
<td>237.7</td>
<td>159.5</td>
<td>-78.2</td>
<td>-32.9%</td>
<td>210.5</td>
<td>75.8%</td>
</tr>
<tr>
<td>Profit before tax</td>
<td>239.2</td>
<td>164.2</td>
<td>-75.0</td>
<td>-31.3%</td>
<td>209.5</td>
<td>78.4%</td>
</tr>
<tr>
<td><strong>Profit</strong></td>
<td>190.0</td>
<td>132.9</td>
<td>-57.1</td>
<td>-30.1%</td>
<td>169.5</td>
<td>78.4%</td>
</tr>
</tbody>
</table>
Main oncology products continue to grow strongly

<table>
<thead>
<tr>
<th>Q3/FY2020 actual (billion yen)</th>
<th>YoY</th>
</tr>
</thead>
<tbody>
<tr>
<td>XTANDI</td>
<td>342.7+44.8</td>
</tr>
<tr>
<td>XOSPATA</td>
<td>17.6+7.9</td>
</tr>
<tr>
<td>PADCEV</td>
<td>9.4+9.4</td>
</tr>
<tr>
<td>mirabegron</td>
<td>122.3+1.3</td>
</tr>
<tr>
<td>New products in Japan</td>
<td>54.1+8.7</td>
</tr>
</tbody>
</table>

Total sales of 3 oncology products, YoY: +62.1 billion yen

Consolidated revenue for Q3/FY2020: -47.6 billion yen, YoY

- Main decrease items
  - Sales decreases due to termination of sales and distribution in Japan (-32.9) and loss of exclusivity (-42.7)
  - Negatively impacted by COVID-19 mainly during Q1/FY2020
### Q3/FY2020 FINANCIAL RESULTS: BUSINESS UPDATE FOR MAIN PRODUCTS

<table>
<thead>
<tr>
<th>Product</th>
<th>Business Update</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>XTANDI</strong></td>
<td>Global sales are in line with forecast. In US, progress against forecast is slightly behind due to the impact of COVID-19 (slowdown of new patient starts), but demand grew in excess of 20% YoY and continued growth is expected. In China, additional indication (M0 CRPC) approved in Nov 2020. To be listed in NRDL for M1 CRPC indication and reimbursement scheduled to start from Mar 2021</td>
</tr>
<tr>
<td><strong>XOSPATA</strong></td>
<td>Sales in US and Europe steadily expanded and global sales are exceeding forecast. Reimbursement has started in UK and Germany. Launched also in Brazil (Aug 2020) and Taiwan (Dec 2020)</td>
</tr>
<tr>
<td><strong>PADCEV</strong></td>
<td>Revenue grew steadily in the first year after launch through rapid market penetration and steady progress against forecast. We have seen strong interest from physicians by positive clinical data recently available. Captured high market share in mUC patients who have previously received a platinum and a PD-1/L1 inhibitor</td>
</tr>
<tr>
<td><strong>Evrenzo</strong></td>
<td>Additional indication in Japan (treatment of anemia of chronic kidney disease in adult patients not on dialysis) approved in Nov 2020. The restriction of 2-week administration period was lifted in Dec 2020. Steadily increasing the number of adopted facilities post approval and sales expansion is expected</td>
</tr>
<tr>
<td><strong>mirabegron</strong></td>
<td>Global sales increased slightly as demand impacted by COVID-19, but in line with forecast. In China, to be listed in NRDL and reimbursement scheduled to start from Mar 2021</td>
</tr>
<tr>
<td><strong>New products in Japan</strong></td>
<td>Sales of EVENITY (+2.6 billion yen) and Suglat-Family (+3.2 billion yen) increased, but progress against forecast is behind due to the impact of COVID-19 such as restrictions on promotion activities, reduction of hospital/clinic visits by patients, etc.</td>
</tr>
</tbody>
</table>

M0: Non-metastatic, M1: Metastatic, CRPC: Castration-resistant prostate cancer, NRDL: National Health Insurance Reimbursed Drug List, mUC: Metastatic urothelial cancer, New products in Japan (Repatha, Suglat-Family, Linzess, Dafclir, BLINCYTO, EVENITY, Smyraf)
Q3/FY2020 FINANCIAL RESULTS: COST ITEMS

Spending of SG&A and R&D expenses is on track to full-year forecast

Core basis: main items for, YoY

Cost of sales
% of revenue
2.5 ppt decrease
✓ Decrease mainly due to changes in product mix
(FX impact on elimination of unrealized gain: Increase in COGs ratio (+0.4 ppt))

SG&A expenses
2.7% increase
✓ XTANDI US co-promotion fee increased due to sales expansion
✓ One-off decrease in FY19 (Reversal of loss allowance: 8.2 bil. yen)
✓ 4.4% decrease, excluding the above

R&D expenses
5.7% increase
✓ Investment increase in development costs for late-stage projects including fezolinetant (Phase 3 studies ongoing)
✓ Audentes’ R&D expenses

FX: Foreign exchange, COGs: Cost of goods sold
AGENDA

I  Q3/FY2020 Consolidated Financial Results

II  Initiatives for Sustainable Growth
enzalutamide

**M0 CRPC**
- Filed in EU in Jun 2020 for label update to include the OS data

**M1 CSPC**
- Filed in EU in Jul 2019

**M0 CSPC**
- Phase 3 study ongoing

**China**
- **M0 CRPC**: Approved in Nov 2020
- **M1 CSPC**: Phase 3 study ongoing

gilteritinib

**R/R AML**
- China: Filed in Mar 2020 (Priority Review granted and listed in “Overseas new drugs urgently needed in clinical settings”)

**Earlier-stage AML**
- Phase 3 studies ongoing. Phase 3 LACEWING study discontinued due to the futility based on the planned interim analysis

enfortumab vedotin

**mUC**
- **Previously treated**: US (sBLA), EU and JP submissions planned in Q4 FY2020. Full data of EV-301 study and EV-201 study cohort 2 to be presented at ASCO GU 2021
- **Previously untreated (first line; combo with pembrolizumab)**: Phase 3 study ongoing
- **China**: IND approved for bridging study and IND accepted for EV-302 study

**MIBC (combo with pembrolizumab)**
- Phase 3 KEYNOTE-905/EV-303 study in cis-ineligible ongoing, and Phase 3 KEYNOTE-B15/EV-304 study in cis-eligible to start in Q4 FY2020

**Other solid tumors**
- Phase 2 study ongoing

zolbetuximab

**Gastric & GEJ adenocarcinoma**
- Phase 3 studies ongoing

**Pancreatic adenocarcinoma**
- Phase 2 study ongoing

roxadustat

**Anemia associated with CKD**
- **EU**: Filed in Apr 2020
- **JP**: Approved for non-dialysis in Nov 2020

**Chemotherapy-induced anemia**
- Phase 2 study ongoing

fezolinetant

**MR-VMS**
- **US & EU**: Phase 3 studies ongoing. 12w DB period topline results for Phase 3 SKYLIGHT 2 study obtained
- **Asia**: Phase 3 studies ongoing

fezolinetant

**AT132 (resamirigene bilparvovec)**

**XLMTM**
- Clinical hold lifted by FDA in Dec 2020. Clinical trial re-start activities underway. Discussions planned on the path forward toward global registration filings
FEZOLINETANT: PHASE 3 STATUS

Three Phase 3 studies in US and EU are progressing well

< SKYLIGHT 2 >
- Enrollment completed
- 12-week DB period topline results obtained:
  - Met the coprimary endpoints for both doses at both timepoints
  - No new safety signals of concern
  => To continue the study for another 40 weeks to mainly evaluate long-term safety as originally planned

< SKYLIGHT 1 >
- Enrollment completed
- LSLV for 12-week DB period achieved
  => 12-week DB period topline results available by end FY2020

< SKYLIGHT 4 >
- Enrollment completed
  => LSLV anticipated in Q4 FY2021

US-NDa and EU-MAa submissions planned based on the long-term data of all these 3 studies

Primary endpoints:
- Mean change in frequency
- Mean change in severity of moderate to severe VMS from baseline to Week 4 and Week 12

Primary endpoints:
- Frequency and severity of adverse events up to Week 55
- % of participants with endometrial hyperplasia and/or endometrial cancer up to Week 52

Two pivotal studies (SKYLIGHT 1 and SKYLIGHT 2)
- Fezolinetant 30 mg n=150
- Fezolinetant 45 mg n=150
- Placebo n=150
- Extension treatment: fezolinetant 30 mg or 45 mg

Long-term safety study (SKYLIGHT 4)
- Fezolinetant 30 mg n=580
- Fezolinetant 45 mg n=580
- Placebo n=580

PROGRESS IN FOCUS AREA APPROACH: IMMUNO-ONCOLOGY PROGRAMS

- Partnership with KaliVir to discover and develop intravenously administered oncolytic virus
- Expanding aAVC platform: Phase 1 study initiation for ASP0739 & ASP7517 in solid tumors

**VET2-L2 from KaliVir Immunotherapeutics**

- VET2-L2 is a vaccinia virus-based oncolytic virus (OV) loaded with a leptin-IL-2 fusion protein
  - that can be delivered intravenously to tumors, eliminating the need for complicated procedures of the direct intra-tumoral administration, enabling access to a broader cancer patient population
  - currently in pre-clinical stage
- Option for the second OV program

**aAVC platform**

- ASP0739: Second aAVC program targeting NY-ESO-1
  - To start Phase 1/2 first-in-human study in advanced solid tumors in mid FY2021
- ASP7517: First aAVC program targeting WT1
  - Phase 1/2 study in R/R AML and MDS ongoing
  - To start Phase 1/2 study in advanced solid tumors in early FY2021

**Mechanism of action of VET2-L2**

- **Intravenously administered virus**
- **Exclusion by host immunity**
- **Cancer cells**
- **Healthy cells**
- **Secretion of immunostimulators (leptin-IL-2)**

**ASTELLAS**

Research collaboration on targeted radiation therapy with Actinium Pharmaceuticals

Development of target-specific radioisotope diagnostics and therapeutics in parallel

- Realize personalized medicine for each patient by directly connecting diagnostic imaging to treatment
- Provide new treatment option for patients resistant to existing treatments
- Prevent recurrence and repeated resection of tumor by detecting and treating small metastasis of cancer cells with high sensitivity and accuracy

PROGRESS IN Rx+ PROGRAM:
DEVELOPMENT OF “THERANOSTICS*”; INTEGRATION OF DIAGNOSTICS AND THERAPEUTICS

Radioisotope diagnostics
- Visualization of tumor with target-specific radioisotope diagnostics
- Diagnosis of small metastasis and tumor position/size with high sensitivity and accuracy
- Preclinical study ongoing

Targeted radiation therapy
- Treatment with target-specific radioisotope therapeutics
- Research collaboration with Actinium Pharmaceuticals, Inc.

* The term that combines “Therapeutics” and “Diagnostics”. Treatment protocol or concept in which healthcare professionals assess lesion sites and simultaneously determine the appropriate treatment for each patient
SUSTAINABILITY: SUPPORT FOR TCFD RECOMMENDATION

Commitment to climate change issues in corporate strategy

Our approach to environment issues

<table>
<thead>
<tr>
<th>- 2017</th>
<th>2018</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kerry plant: Wind turbine, Wood chip biomass boiler</td>
<td>GHG reduction targets approved by SBT</td>
<td>Purchasing electricity from renewable energy</td>
<td>Support for TCFD recommendation</td>
</tr>
<tr>
<td>Hybrid cars for sales reps</td>
<td>GHG reduction targets approved by SBT</td>
<td>GHG reduction in 3 domestic facilities</td>
<td>CSP incorporating sustainability</td>
</tr>
<tr>
<td></td>
<td>Targets in 2030 covering all business activities</td>
<td></td>
<td>Commitment to climate change related disclosure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>To announce in May</td>
</tr>
</tbody>
</table>

Engagement by improved disclosure

To improve disclosure on scenario-based environmental risk/opportunity

Core elements in TCFD recommendation

- Governance
- Risk management
- Metrics and targets
- Strategy (risk/opportunity analysis etc.)

TCFD: Task Force on Climate-related Financial Disclosures, GHG: Greenhouse gas, SBT: Science Based Targets, CSP: Corporate Strategic Plan
SCHEDULE

Apr 27\textsuperscript{th}, 2021: Financial Results for FY2020

May 26\textsuperscript{th}, 2021: New Corporate Strategic Plan
Q3/FY2020: REVENUE BY REGION

<table>
<thead>
<tr>
<th>Region</th>
<th>(billion yen) Q3/FY19</th>
<th>Q3/FY20</th>
<th>Change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>276.2</td>
<td>221.8</td>
<td>-19.7%</td>
</tr>
<tr>
<td>United States</td>
<td>331.9</td>
<td>355.8</td>
<td>+7.2%</td>
</tr>
<tr>
<td>Established Markets</td>
<td>218.0</td>
<td>218.0</td>
<td>-0.0%</td>
</tr>
<tr>
<td>Greater China</td>
<td>44.4</td>
<td>43.8</td>
<td>-1.2%</td>
</tr>
<tr>
<td>International</td>
<td>102.8</td>
<td>87.6</td>
<td>-14.8%</td>
</tr>
</tbody>
</table>

Established Markets: Europe, Canada, Australia
Greater China: China, Hong Kong, Taiwan
International: Russia, Latin America, Middle East, Africa, South East Asia, South Asia, Korea, Export sales, etc.
## Q3/FY2020: SALES OF MAIN PRODUCTS

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q3/FY19</th>
<th>Q3/FY20</th>
<th>Change</th>
<th>CER growth</th>
<th>FY20 FCST*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>XTANDI</strong></td>
<td>297.9</td>
<td>342.7</td>
<td>+15.0%</td>
<td>+16.2%</td>
<td>464.6</td>
</tr>
<tr>
<td><strong>XOSPATA</strong></td>
<td>9.8</td>
<td>17.6</td>
<td>+80.7%</td>
<td>+83.3%</td>
<td>23.1</td>
</tr>
<tr>
<td><strong>PADCEV</strong></td>
<td>0.0</td>
<td>9.4</td>
<td>-</td>
<td>-</td>
<td>13.0</td>
</tr>
<tr>
<td><strong>OAB products</strong></td>
<td>157.2</td>
<td>147.0</td>
<td>-6.5%</td>
<td>-5.5%</td>
<td>197.9</td>
</tr>
<tr>
<td>mirabegron</td>
<td>121.0</td>
<td>122.3</td>
<td>+1.0%</td>
<td>+2.3%</td>
<td>167.9</td>
</tr>
<tr>
<td>Vesicare</td>
<td>36.2</td>
<td>24.7</td>
<td>-31.8%</td>
<td>-31.7%</td>
<td>30.0</td>
</tr>
<tr>
<td><strong>Prograf</strong></td>
<td>146.2</td>
<td>138.3</td>
<td>-5.4%</td>
<td>-5.3%</td>
<td>182.0</td>
</tr>
</tbody>
</table>

PADCEV: Co-promotion revenue from Seagen
OAB (overactive bladder) products: Vesicare + mirabegron (Product name: Betanis/Myrbetriq/BETMIGA)
Prograf: Incl. Advagraf/Graceptor/ASTAGRAF XL

*Announced in Aug 2020
## Q3/FY2020 ACTUAL: FX RATE

### Average rate for the period

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q3/FY19</th>
<th>Q3/FY20</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>109 yen</td>
<td>106 yen</td>
<td>-3 yen</td>
</tr>
<tr>
<td>EUR</td>
<td>121 yen</td>
<td>122 yen</td>
<td>+1 yen</td>
</tr>
</tbody>
</table>

### Change in closing rate from previous fiscal year end

<table>
<thead>
<tr>
<th>Currency</th>
<th>Q3/FY19</th>
<th>Q3/FY20</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD</td>
<td>-1 yen</td>
<td>-5 yen</td>
<td></td>
</tr>
<tr>
<td>EUR</td>
<td>-2 yen</td>
<td>+7 yen</td>
<td></td>
</tr>
</tbody>
</table>

**<Impact of exchange rate on financial results>**

- 7.3 billion yen decrease in revenue, 3.6 billion yen decrease in core OP
- FX impact on elimination of unrealized gain: COGs ratio +0.4 ppt

FX: Foreign exchange, COGs: Cost of goods sold
## FY2020 FCST: FX RATE & FX SENSITIVITY

### Exchange rate (yen) Average for the period | FY20 FCST
---|---
USD | 109 yen
EUR | 120 yen

Forecast rates from Q2/FY2020 onwards: 110 USD/yen, 120 EUR/yen

### Estimated FX sensitivity (Q2 and onward) of FY2020 revised forecasts by 1 yen appreciation *

<table>
<thead>
<tr>
<th>Currency</th>
<th>Average rate 1 yen higher than assumption</th>
<th>Year-end rate 1 yen higher than assumption</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Revenue</td>
<td>Core OP</td>
</tr>
<tr>
<td>USD</td>
<td>Approx. -4.3 bil. yen</td>
<td>Approx. -0.8 bil. yen</td>
</tr>
<tr>
<td>EUR</td>
<td>Approx. -2.0 bil. yen</td>
<td>Approx. -0.8 bil. yen</td>
</tr>
</tbody>
</table>

* Sensitivity to fluctuation of FX rates used for consolidation of overseas affiliates’ results compared to forecasted rates from Q2/FY2020 and onwards
## BALANCE SHEET & CASH FLOW HIGHLIGHTS

### FY19 end vs Dec 31, 2020

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Dec 31, 2020</th>
<th>FY19 end</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total assets</td>
<td>2,296.8</td>
<td>2,315.2</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>306.5</td>
<td>318.4</td>
</tr>
<tr>
<td>Total equity attributable to owners of the parent</td>
<td>1,368.6</td>
<td>1,289.2</td>
</tr>
<tr>
<td>Equity ratio (%)</td>
<td>59.6%</td>
<td>55.7%</td>
</tr>
</tbody>
</table>

### Q3/FY19 vs Q3/FY20 vs FY19

<table>
<thead>
<tr>
<th>(billion yen)</th>
<th>Q3/FY19</th>
<th>Q3/FY20</th>
<th>FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities</td>
<td>170.3</td>
<td>225.1</td>
<td>222.0</td>
</tr>
<tr>
<td>Cash flows from investing activities</td>
<td>-74.4</td>
<td>-67.7</td>
<td>-389.8</td>
</tr>
<tr>
<td>Free cash flows</td>
<td>95.9</td>
<td>157.4</td>
<td>-167.8</td>
</tr>
<tr>
<td>Cash flows from financing activities</td>
<td>-125.2</td>
<td>-171.3</td>
<td>181.1</td>
</tr>
<tr>
<td>Bonds and short-term borrowings</td>
<td>-</td>
<td>-161.0</td>
<td>326.0</td>
</tr>
<tr>
<td>Proceeds from long-term borrowings</td>
<td>-</td>
<td>80.0</td>
<td>-</td>
</tr>
<tr>
<td>Dividends paid</td>
<td>-73.5</td>
<td>-76.2</td>
<td>-73.5</td>
</tr>
</tbody>
</table>
Top priority is investment for strategic business growth

Dividends to be increased continuously based on mid-and long-term growth

Share buybacks to be implemented in a flexible manner

Pursue business development opportunities in line with our strategy

Steady dividend increase

Flexible buybacks considering the cash balance
## DETAILS OF SHAREHOLDER RETURNS

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Dividends (yen)</th>
<th>Acquisition of Own Share (yen)</th>
<th>Total Return Ratio (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY05</td>
<td>39.3</td>
<td>46.2</td>
<td>82</td>
</tr>
<tr>
<td>FY06</td>
<td>42.3</td>
<td>219.9</td>
<td>200</td>
</tr>
<tr>
<td>FY07</td>
<td>55.2</td>
<td>81.8</td>
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<tr>
<td>FY08</td>
<td>56.9</td>
<td>123.4</td>
<td>106</td>
</tr>
<tr>
<td>FY09</td>
<td>58.2</td>
<td>27.0</td>
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</tr>
<tr>
<td>FY10</td>
<td>57.7</td>
<td>-</td>
<td>85</td>
</tr>
<tr>
<td>FY11</td>
<td>57.7</td>
<td>-</td>
<td>74</td>
</tr>
<tr>
<td>FY12</td>
<td>59.4</td>
<td>-</td>
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<tr>
<td>FY13</td>
<td>60.6</td>
<td>-</td>
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<tr>
<td>FY14</td>
<td>66.0</td>
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<td>FY15</td>
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<td>FY17</td>
<td>72.1</td>
<td>119.3</td>
<td>123</td>
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<td>FY18</td>
<td>72.4</td>
<td>91.4</td>
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<td>FY19</td>
<td>75.0</td>
<td>130.0</td>
<td>64</td>
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<tr>
<td>FY20       (FCST)</td>
<td>78.0</td>
<td>160.0</td>
<td></td>
</tr>
</tbody>
</table>

* The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of Apr 1, 2014. Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of FY2005.

** From FY2013, figures are in accordance with International Financial Reporting Standards (IFRS).
### FILING OPPORTUNITIES
### ANNOUNCED IN STRATEGIC PLAN 2018

**As of Jan 2021**

- **✓✓✓**: Approved
- **✓✓**: Filed
- **✓**: Data obtained, filing under preparation

<table>
<thead>
<tr>
<th>Drug</th>
<th>Status</th>
<th>Therapeutic area</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>enzalutamide</strong></td>
<td></td>
<td>Oncology, Nephrology, Others</td>
</tr>
<tr>
<td><strong>M0 CRPC</strong></td>
<td>✓✓✓</td>
<td></td>
</tr>
<tr>
<td><strong>gilteritinib</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>R/R AML</strong></td>
<td>✓✓✓</td>
<td></td>
</tr>
<tr>
<td><strong>roxadustat</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anemia associated with CKD</strong></td>
<td>✓✓✓</td>
<td></td>
</tr>
<tr>
<td><strong>Dialysis (JP)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>enfortumab vedotin</strong></td>
<td>✓✓✓</td>
<td>Oncology</td>
</tr>
<tr>
<td><strong>Metastatic urothelial cancer</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>Platinum and PD-1/L1 inhibitor pretreated (US)</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>gilteritinib</strong></td>
<td></td>
<td>Oncology, Nephrology, Others</td>
</tr>
<tr>
<td><strong>AML</strong></td>
<td>^ Post-HSCT maintenance</td>
<td></td>
</tr>
<tr>
<td><strong>Post-chemo maintenance</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>AML (1st line low intensity induction chemo)</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>AML (1st line high intensity induction chemo)</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>zolbetuximab</strong></td>
<td></td>
<td>Oncology, Nephrology, Others</td>
</tr>
<tr>
<td><strong>Gastric and gastroesophageal junction adenocarcinoma</strong></td>
<td>✓✓✓</td>
<td>Oncology</td>
</tr>
<tr>
<td><strong>roxadustat</strong></td>
<td></td>
<td>Oncology, Nephrology, Others</td>
</tr>
<tr>
<td><strong>Anemia associated with CKD</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>Non-dialysis (JP)</strong></td>
<td>✓✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>Dialysis/Non-dialysis (EU)</strong></td>
<td>✓✓</td>
<td>Onco</td>
</tr>
<tr>
<td><strong>fezolinetant</strong></td>
<td></td>
<td>Oncology, Nephrology, Others</td>
</tr>
<tr>
<td><strong>MR-VMS</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FY2018**

**FY2019-2020**

**FY2021 or beyond**

**Note)** Subject to internal assessment, decision and regulatory consultation, as appropriate. Filing (submission) timing in the first country/region within US/EU/JP

**M0**: Non-metastatic, **M1**: Metastatic, **CRPC**: Castration-resistant prostate cancer, **CSPC**: Castration-sensitive prostate cancer, **R/R**: Relapsed or refractory, **AML**: Acute myeloid leukemia, **CKD**: Chronic kidney disease, **HSCT**: Hematopoietic stem cell transplantation, **MR-VMS**: Menopause related vasomotor symptoms
## ROBUST PIPELINE OF ASTELLAS

### Phase 1
- ASP1948/PTZ-329
- ASP1951/PTZ-522
- ASP9801
- ASP7517
- ASP0739
- ASP7317
- ASP0892
- ASP0367/MA-0211 (DMD)
- ASP2390
- ASP0598
- AT845
- ASP8062
- ASP1617

### Phase 2
- zolbetuximab (Pancreatic adenocarcinoma)
- enfortumab vedotin (Other solid tumors)
- ASP1128/MA-0217 (Acute kidney injury)
- ASP3772 (Pneumococcal disease)
- FX-322 (Sensorineural hearing loss)
- resamirigene bilparvovec/AT132 (XLMTM)
- ASP0367/MA-0211 (Primary mitochondrial myopathies)
- bleselumab (rFSGS)
- roxadustat (Chemotherapy-induced anemia)
- isavuconazole (Pediatric use: US)

### Phase 3
- enzalutamide (M0 CSPC, M1 CSPC: China)
- gilteritinib (Earlier-stage AML, Pediatric use)
- enfortumab vedotin (mUC, MIBC)
- zolbetuximab (Gastric and GEJ adenocarcinoma)
- peficitinib (Rheumatoid arthritis: China)
- mirabegron (Pediatric use: EU)
- fezolinetant (MR-VMS)

### Filed
- enzalutamide (M1 CSPC: EU)
- gilteritinib (R/R AML: China)
- roxadustat (Anemia associated with CKD: EU)
- mirabegron (Pediatric NDO: US)
- tacrolimus (Lung transplantation: US)

Please refer to R&D pipeline list for details including target disease.

PROGRESS IN OVERALL PIPELINE
Phase 1 Entry to Approval since Q2/FY2020 Financial Results Announcement in Oct 2020

<table>
<thead>
<tr>
<th>Phase 1 Entry</th>
<th>Phase 2 Entry</th>
<th>Phase 3 Entry</th>
<th>Filing</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASP0739</td>
<td></td>
<td></td>
<td></td>
<td>enzalutamide</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
<td></td>
<td>Nonmetastatic cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>castration-resistant prostate cancer: China</td>
</tr>
<tr>
<td></td>
<td>tacrolimus</td>
<td></td>
<td></td>
<td>roxadustat</td>
</tr>
</tbody>
</table>

Note: Phase 1 entry is defined as confirmation of IND open. Phase transition is defined by approval of company decision body for entering to next clinical phase. Filing is defined as submission of application to health authorities. Discontinuation is defined by the decision of company decision body.

IND: Investigational new drug
ENZALUTAMIDE: ANDROGEN RECEPTOR INHIBITOR (1/2)

US/EU/JP

Initial Diagnosis

Active Surveillance

Definitive Therapy

Surgery

Salvage

Radiation

Castration-Sensitive

ARCHES

M1 CSPC newly-diagnosed

M1 CSPC recurrent

Launched in US & JP
Filed in EU

EMBARK

M0 CSPC

Castration-Resistant

PREVAIL
M1 CRPC (1st line)

Launched

AFFIRM
M1 CRPC (2nd line+)

Launched

P3: ARCHES  M1 CSPC  Combo with ADT, vs. placebo  n=1,150  Approved in US in Dec 2019 and in JP in May 2020  Filed in EU in Jul 2019

P3: EMBARK  M0 CSPC  Combo with ADT, vs. placebo  n=1,068  Enrollment completed

China

- M1 CRPC: Approved in Nov 2019 and launched in Mar 2020
- M0 CRPC: Approved in Nov 2020
- M1 CSPC: Enrollment completed in Phase 3 China-ARCHES study

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020
M1: Metastatic, M0: Non-metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, ADT: Androgen deprivation therapy
ENZALUTAMIDE (2/2): PHASE 3 STUDY DATA BY DISEASE STAGE

Continued potential in earlier lines with consistent survival benefit and longer duration of treatment

<table>
<thead>
<tr>
<th>Disease stage</th>
<th>Early stage</th>
<th>Late stage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Castration-sensitive (CSPC)</td>
<td>Castration-resistant (CRPC)</td>
</tr>
<tr>
<td></td>
<td>M0</td>
<td>M1</td>
</tr>
<tr>
<td>Phase 3 study</td>
<td>EMBARK</td>
<td>ARCHES</td>
</tr>
<tr>
<td>Control</td>
<td>Placebo</td>
<td>Placebo</td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>MFS (Ongoing)</td>
<td>✓ rPFS HR 0.39</td>
</tr>
<tr>
<td></td>
<td>(Not reached)</td>
<td>(Not reached)</td>
</tr>
<tr>
<td>OS</td>
<td>(Ongoing)</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td>(Not reached)</td>
<td></td>
</tr>
<tr>
<td>DoT</td>
<td>(Ongoing)</td>
<td>(Not reached)</td>
</tr>
<tr>
<td></td>
<td>(Not reached)</td>
<td></td>
</tr>
</tbody>
</table>

✓: Data obtained, *: Prespecified interim analysis

M0: Non-metastatic, M1: Metastatic, CSPC: Castration-sensitive prostate cancer, CRPC: Castration-resistant prostate cancer, NSAA: Non-steroidal antiandrogen, HR: Hazard ratio, MFS: Metastasis-free survival, rPFS: Radiographic progression-free survival, OS: Overall survival, DoT: Duration of treatment
**Gilteritinib: FLT3 Inhibitor**

- **Relapsed or refractory**
  - P3: ADMIRAL
    - Monotherapy vs salvage chemo (2:1)
    - n=371
    - Launched in US, JP, and EU. Filed in China in Mar 2020 (Priority Review granted and listed in “Overseas new drugs urgently needed in clinical settings”)

- **Newly diagnosed (intensive chemo eligible)**
  - P3: PASHA (HOVON)
    - Combo with high intensity chemo gilteritinib vs. midostaurin (1:1)
    - n=768
    - FSFT: Dec 2019 (Sponsor: HOVON)
  - P2: PrE0905 (PrECOG)
    - n=179
    - FSFT: Dec 2019 (Sponsor: PrECOG, LLC.)

- **Newly diagnosed (intensive chemo ineligible)**
  - P3: LACEWING
    - Combo with azacitidine vs. azacitidine alone (2:1)
    - n=146
    - Discontinued due to the futility based on the planned interim analysis

- **Post-HSCT maintenance**
  - P3: MORPHO
    - Monotherapy vs. placebo (1:1)
    - n=346
    - Enrollment completed
    - Collaborating with BMT-CTN

- **Post-chemo maintenance**
  - P2: GOSSAMER
    - Monotherapy vs. placebo (2:1)
    - n=98
    - Enrollment completed

---

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020

FLT3 mut+: FLT3 mutation positive, AML: Acute myeloid leukemia, FSFT: First subject first treatment, HSCT: Hematopoietic stem cell transplant, HOVON: The Haemato Oncology Foundation for Adults in the Netherlands, BMT-CTN: Blood and Marrow Transplant - Clinical Trial Network
# ENFORTUMAB VEDOTIN (EV) : NECTIN-4 TARGETED ADC (1/5)

## For urothelial cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>n</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P3: EV-301</strong></td>
<td>mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono vs. Chemo</td>
<td>608</td>
<td>Met the primary endpoint (OS) in Sep 2020, based on the planned interim analysis (full data to be presented at ASCO GU 2021)</td>
</tr>
<tr>
<td><strong>P3: EV-302</strong></td>
<td>mUC, Previously untreated, Platinum-eligible; EV + Pembrolizumab vs. Chemo</td>
<td>760</td>
<td>FSFT: Apr 2020</td>
</tr>
<tr>
<td><strong>P3: EV-303</strong> /<strong>KEYNOTE-905</strong></td>
<td>MIBC, Cis-ineligible; Pembrolizumab +/- EV (perioperative) + RC vs. RC alone</td>
<td>836</td>
<td>Enrollment ongoing in Pembrolizumab + EV arm</td>
</tr>
<tr>
<td><strong>P3: EV-304</strong> /<strong>KEYNOTE-B15</strong></td>
<td>MIBC, Cis-eligible; EV+Pembrolizumab (perioperative) + RC vs. Chemo (neoadjuvant) + RC</td>
<td>784</td>
<td>To start in Q4 FY2020</td>
</tr>
<tr>
<td><strong>P2: EV-201</strong></td>
<td>mUC, PD-1/L1 inhibitor pretreated; EV mono Cohort 1: Platinum pretreated Cohort 2: Platinum naive and cis-ineligible</td>
<td>219</td>
<td>Cohort 1: Approved (under the Accelerated Approval program) and launched in US in Dec 2019 Cohort 2: Obtained positive ORR in Oct 2020 (full data to be presented at ASCO GU 2021)</td>
</tr>
<tr>
<td><strong>P2: EV-203</strong></td>
<td>Bridging study in China mUC, Platinum and PD-1/L1 inhibitor pretreated; EV mono</td>
<td>40</td>
<td>Currently under preparation (IND approved)</td>
</tr>
</tbody>
</table>

## For other solid tumors

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>n</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P2: EV-202</strong></td>
<td>HR+/HER2- breast cancer, Triple-negative breast cancer, Squamous NSCLC, Non-squamous NSCLC, Head and neck cancer, Gastric, gastroesophageal junction or esophageal cancer; EV mono</td>
<td>240</td>
<td>FSFT: Mar 2020</td>
</tr>
</tbody>
</table>

**Underlined**: Updates since Q2/FY2020 financial results announcement in Oct 2020

ENFORTUMAB VEDOTIN (EV) (2/5): OVERALL mUC PROGRAM

### Early stage

- **NMIBC**
  - Stages 0a-1
    - Ta: Noninvasive papillary carcinoma
    - Tis: Carcinoma in situ
    - T1: Tumor invades lamina propria

- **MIBC**
  - Stages 2 and 3
    - T2: Tumor invades muscle
    - T3: Tumor invades perivesical fat
    - T4a: Tumor invades contiguous organs (prostate, uterus, vagina)

### Late stage

- **mUC**
  - Stage 4
    - T4b: Tumor invades pelvic wall, abdominal wall
    - N1-3: Any lymph node involvement
    - M1: Distant metastases

### Clinical studies for EV

- **mUC patient treatment**
  - Previously untreated (first line)
    - EV + Pembro combo
  - PD-1/L1 inhibitor pretreated
    - EV mono
  - Platinum and PD-1/L1 inhibitor pretreated
    - EV mono

- **Target EV regimen**
  - P3: EV-302
    - Platinum-eligible, vs. Chemo
  - P1b/2: EV-103
    - (Dose escalation cohort and Cohort A)
      - Cis-ineligible
    - (Cohort K)
      - Cis-ineligible
      - EV mono vs. EV + Pembro
  - P2: EV-201 (Cohort 2)
    - Platinum-naïve and cis-ineligible
  - P2: EV-201 (Cohort 1)
  - P3: EV-301
    - vs. Chemo
  - P2: EV-203
    - (Bridging study in China)

- **Approved (AA) & launched in US**

**mUC**: Metastatic urothelial cancer, **NMIBC**: Non-muscle-invasive bladder cancer, **MIBC**: Muscle-invasive bladder cancer, **mono**: Monotherapy, **Pembro**: Pembrolizumab, **Cis**: Cisplatin, **Chemo**: Chemotherapy, **AA**: Accelerated Approval, **ORR**: Objective response rate, **OS**: Overall survival.
ENFORTUMAB VEDOTIN (EV) (3/5): CLINICAL STUDIES IN MIBC

1) Phase 3 study in cis-ineligible MIBC (KEYNOTE-905/EV-303): Perioperative EV+Pembro vs. Cystectomy alone

- **Endpoints:**
  - Primary (dual): EFS and pCR
  - Key secondary: OS
- **n=836, randomized 1:1:1**
- **Arm C added to the ongoing Merck-sponsored KEYNOTE-905 study => Enrollment ongoing in Arm C**

2) Phase 3 study in cis-eligible MIBC (KEYNOTE-B15/EV-304): Perioperative EV+Pembro vs. Neoadjuvant chemo

- **Endpoints:**
  - Primary (dual): EFS and pCR
  - Key secondary: OS
- **n=784, randomized 1:1**
- **Sponsored by Merck. Funded by 3 companies: Seagen, Astellas, and Merck**
- **Study start planned in Q4 FY2020**

3) Phase 1b/2 study in cis-ineligible MIBC (cohorts in EV-103): Neoadjuvant/Perioperative EV mono

- **To assess EV monotherapy in MIBC to support the EV+Pembro combo treatment outcome**
- **Primary endpoint: pCR**
- **Cohort L newly added to the ongoing Seagen-sponsored EV-103 study to start in 1H 2021**

**Underlined:** Updates since Q2/FY2020 financial results announcement in Oct 2020
## ENFORTUMAB VEDOTIN (EV) (4/5): PHASE 1b/2 EV-103 STUDY DESIGN

<table>
<thead>
<tr>
<th>Dose Escalation Cohort</th>
<th>Dose Expansion Cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Locally advanced or metastatic urothelial cancer</strong></td>
<td><strong>Cohort A</strong> EV + Pembro Cis-ineligible 1L or 2L <strong>Cohort D</strong> EV + Cis, 1L <strong>Cohort G</strong> EV + Cis/Carbo + Pembro 1L</td>
</tr>
<tr>
<td>EV + Pembro Cis-ineligible 1L or 2L</td>
<td><strong>Cohort E</strong> EV + Carbo, 1L <strong>Optional Cohort B</strong> EV + gemcitabine 1L or 2L</td>
</tr>
<tr>
<td><strong>Cohort K</strong> EV mono vs. EV+Pembro (1:1, n=150 in total) Cis-ineligible, 1L</td>
<td><strong>Optional Cohort J</strong> EV+Pembro (neoadjuvant) + RC Cis-ineligible <strong>Cohort L</strong> EV mono (perioperative) + RC Cis-ineligible</td>
</tr>
<tr>
<td><strong>Cohort H</strong> EV mono (neoadjuvant) + RC Cis-ineligible</td>
<td></td>
</tr>
<tr>
<td><strong>Muscle-invasive bladder cancer</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended EV dose</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Results from cis-ineligible and 1L in these cohorts presented at ESMO 2019 and ASCO GU 2020

### Data from Cohort K, along with other data from the EV-103 study evaluating EV combined with pembrolizumab as first-line therapy for cisplatin-ineligible patients, could potentially support registration under Accelerated Approval regulations in US

---

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020
Pembro: pembrolizumab, 1L: First line, 2L: Second line, Cis: Cisplatin, Carbo: Carboplatin, mono: Monotherapy, RC: Radical cystectomy, ESMO: European Society for Medical Oncology, ASCO GU: Genitourinary Cancers Symposium of the American Society of Clinical Oncology

(EV-103 study is sponsored by Seagen)
## ENFORTUMAB VEDOTIN (5/5): NUMBER OF UC PATIENTS

<table>
<thead>
<tr>
<th>Urothelial cancer (Annual)</th>
<th>All stages (Incidence)</th>
<th>MIBC</th>
<th>mUC</th>
<th>Drug treated (1L)</th>
<th>Drug treated (2L+*)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Post-cystectomy</td>
<td>Total (Incident + Newly recurrent)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>US</strong></td>
<td>79,000</td>
<td>20,000</td>
<td>19,000</td>
<td>15,000</td>
<td>8,000</td>
</tr>
<tr>
<td><strong>EU5</strong></td>
<td>118,000</td>
<td>32,000</td>
<td>29,000</td>
<td>27,000</td>
<td>12,000</td>
</tr>
<tr>
<td><strong>JP</strong></td>
<td>39,000</td>
<td>10,000</td>
<td>8,000</td>
<td>7,000</td>
<td>3,000</td>
</tr>
<tr>
<td><strong>China</strong></td>
<td>101,000</td>
<td>24,000</td>
<td>29,000</td>
<td>24,000</td>
<td>9,000</td>
</tr>
</tbody>
</table>

*Number of drug-treated patients expected to rise after new drug launch*

Kantar Health incident and newly recurrent patients
(m)UC: (Metastatic) urothelial cancer, MIBC: Muscle-invasive bladder cancer

*2L+: Platinum and/or PD-1/L1 inhibitor pretreated*
# ZOLBETUXIMAB: ANTI-CLAUDIN 18.2 MONOCLONAL ANTIBODY

## Target: Claudin 18.2
- Claudin is a major structural component of tight junctions and seals intercellular space in epithelial sheets
- Broadly expressed in various cancer types
  - ~70% of gastric tumors; ~30% of these meet the eligibility criteria for the ongoing Phase 3 studies
  - ~60% of primary pancreatic adenocarcinomas; approx. 20% of these meet the eligibility criteria for the ongoing Phase 2 study

## Gastric and gastroesophageal junction (GEJ) adenocarcinoma
- Target patient population: locally advanced and metastatic gastric and GEJ adenocarcinoma with high Claudin 18.2 expression
- Gastric cancer is the third leading cause of cancer death worldwide
- Overall 5-year survival rate for metastatic gastric and GEJ cancer is under 20%
- Median overall survival for Stage IV gastric cancer is 10-15 months

<table>
<thead>
<tr>
<th>Gastric and GEJ adenocarcinoma</th>
<th>P3: SPOTLIGHT</th>
<th>First line, combo with mFOLFOX6, vs. placebo</th>
<th>n=550</th>
<th>FSFT: Oct 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: GLOW</td>
<td>First line, combo with CAPOX, vs. placebo</td>
<td>n=500</td>
<td>FSFT: Jan 2019</td>
<td></td>
</tr>
<tr>
<td>P2: ILUSTRO</td>
<td>Cohort 1: Third or later line, zolbetuximab monotherapy Cohort 2: First line, combo with mFOLFOX6 Cohort 3: Third or later line, combo with pembrolizumab</td>
<td>n=112</td>
<td>FSFT: Sep 2018</td>
<td></td>
</tr>
<tr>
<td>Pancreatic adenocarcinoma</td>
<td>P2</td>
<td>Combo with nab-paclitaxel and gemcitabine, vs. placebo</td>
<td>n=141</td>
<td>FSFT: May 2019</td>
</tr>
</tbody>
</table>

mFOLFOX6: 5-FU, leucovorin and oxaliplatin, CAPOX: Capecitabine and oxaliplatin, FSFT: First subject first treatment
FEZOLINETANT: NK3 RECEPTOR ANTAGONIST

VMS has a significant negative impact on quality of life

- Physical symptoms include hot flashes and sweating/night sweats, which can impact sleep.
- Physical symptoms lead to emotional impact including embarrassment, irritability, anxiety, and sadness.
- Symptoms have a negative impact on multiple aspects of everyday life.

Women’s Health Initiative (WHI) Study

- Initial data analyses showed an association between chronic HRT use and increased risk of cardiovascular disease and cancer.
- Since WHI’s findings, no replacement for HRT with similar efficacy and no significant safety concern, resulting in huge unmet medical needs.

US and EU

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Period</th>
<th>Patients</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: SKYLIGHT 1</td>
<td>Moderate to severe MR-VMS; The first 12 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)</td>
<td>n=527</td>
<td>LSLV for 12w DB period achieved</td>
<td></td>
</tr>
<tr>
<td>P3: SKYLIGHT 2</td>
<td>Moderate to severe MR-VMS; The first 12 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)</td>
<td>n=501</td>
<td>12w DB period topline results obtained</td>
<td></td>
</tr>
<tr>
<td>P3: SKYLIGHT 4</td>
<td>MR-VMS; 52 weeks: DB, 30 mg vs. 45 mg vs. placebo (1:1:1)</td>
<td>n=1,833</td>
<td>Enrollment completed</td>
<td></td>
</tr>
</tbody>
</table>

Asia (except for Japan)

<table>
<thead>
<tr>
<th>Study</th>
<th>Condition</th>
<th>Period</th>
<th>Patients</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>P3: MOONLIGHT 1</td>
<td>Moderate to severe MR-VMS; The first 12 weeks: DB, 30 mg vs. placebo (1:1)</td>
<td>n=300</td>
<td>FSFT: Apr 2020</td>
<td></td>
</tr>
<tr>
<td>P3: MOONLIGHT 3</td>
<td>MR-VMS; open label, 30 mg for 52 weeks</td>
<td>n=150</td>
<td>FSFT: Aug 2020</td>
<td></td>
</tr>
</tbody>
</table>

JP: Independent development plan under preparation

Underlined: Updates since Q2/FY2020 financial results announcement in Oct 2020


AT132 (RESAMIRIGENE BILPARVOVEC): rAAV8-Des-hMTM1

**Characteristics of AT132**

- Lead program in the gene therapy pipeline of Audentes Therapeutics, acquired by Astellas in Jan 2020
- Designed to deliver a functional copy of human MTM1 gene by AAV8 to transfect and express myotubularin in skeletal muscle cells
- Regulatory designations granted:
  - ✓ <US> RMAT, Rare Pediatric Disease, Fast Track, and Orphan Drug designations
  - ✓ <EU> PRIME and Orphan Drug designations

**X-linked myotubular myopathy (XLMTM)**

- Rare neuromuscular disease with X-linked, loss of function mutations in MTM1 gene
  - ✓ Approximately 1 in 40,000 to 50,000 newborn males
  - ✓ Estimated 50% mortality by 18 months
- > 80% require ventilator support
- Motor milestones substantially delayed
- No treatment available; supportive care only

**ASPIRO**

<table>
<thead>
<tr>
<th>Clinical study for registration in XLMTM patients</th>
<th>n=26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical hold lifted by FDA in Dec 2020.</td>
<td></td>
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<tr>
<td>Clinical trial re-start activities underway</td>
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<tr>
<td>Discussions planned on the path forward toward global registration filings</td>
<td></td>
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</tbody>
</table>
ON THE FOREFRONT OF HEALTHCARE CHANGE